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APPENDIX X.X.X.

GENERAL GUIDELINES FOR AQUATIC ANIMAL HEALTH SURVEILLANCE

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Article 3.8.1.5.

Structured non-random surveillance

Surveillance systems routinely use structured non-random data, either alone or in combination with surveys.

1. ...

3. Analytical methodologies

Different scientifically valid methodologies may be used for the analysis of non-random surveillance data. This most often requires information on parameters of importance to the surveillance system, such as sensitivity and specificity and prior probabilities of infection (e.g., for negative predictive value calculations). Where no such data are available, estimates based on expert opinions, gathered and combined using a formal, documented and scientifically valid methodology may be used.

Rationale: For completeness, the United States recommends adding the indicated text.

4. Combination of multiple sources of data

The methodology used to combine the evidence from multiple or recurrent (e.g., time series) data sources should be scientifically valid, and fully documented including references to published material.

Rationale: need to specify other sources of data.

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Article 3.8.1.6.

Surveillance to demonstrate freedom from disease/infection

USA Comments – Aquatic Animals Health Standards Commission

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2. Requirements to declare a country, zone or compartment free from disease/infection without pathogen specific surveillance

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c) Last occurrence within the previous 25 years

Countries, zones or compartments that have achieved eradication (or in which the disease/infection has ceased to occur) within the previous 25 years, should follow the pathogen-specific surveillance requirements in the Aquatic Manual if they exist.

In the absence of *disease* specific information to aid the development of a surveillance system, declaration of disease freedom should follow at least 2 surveys per year (for at least consecutive years)to be conducted more months apart, at the appropriate life stage and at times of the year when temperature and season offer the best opportunity to detect the pathogen. Surveys should be designed to provide an overall 95% confidence and with a design prevalence at the animal and higher (i.e. pond, farm, village, etc.) levels being 2% or lower (this value may be different for different diseases and may be provided in the specific disease chapter in the Aquatic Manual). Such surveys should not be based on voluntary submission and should be developed following the guidelines provided in the Aquatic Manual. Survey results will provide sufficient evidence of disease freedom provided that for at least the past 10 years these additional criteria are met:

- i) the basic biosecurity conditions are in place and effectively enforced;
- ii) no vaccination against the *disease* has been carried out unless otherwise provided in the *Aquatic Code*;
- iii) infection is not known to be established in wild aquatic animals within the country or zone intended to be declared free. (A country or zone cannot apply for freedom if there is any evidence of infection in wild aquatic animals. Specific surveillance in wild aquatic animals of susceptible species is necessary to confirm absence.)

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General Comment: While this section (above text) refers to "disease" in wild populations, this appendix does not provide clear guidelines for surveillance in wild aquatic animal populations. Knowledge of the disease status in wild populations is critical to assessing the threat of a given disease to farmed animals. The application of general surveillance guidelines (e.g., detection, threshold assumptions, probability based sampling, boundaries) to wild aquatic populations is not a seamless transition. Therefore, a "special considerations" section for wild aquatic population surveillance is a section still needing development.